K052544

Supporting Clinical Engineering Worldwide

SEP 29 2006

510(k) Summary

Submitter Information:

American IV Products, Inc.
7485 Shipley Avenue
Hanover, MD 21076

Contact:

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Date Prepared:

September 15, 2005

Product Name:

Classification Name: Pulse Oximeter Adapter Cables
Common Name: Pulse Oximeter Adapter Cables
Proprietary Name: Pulse Oximeter Adapter Cables

Predicate Device:

These AIV devices are equivalent to the following legally marketed devices:

Criticare Model: 518DD – K001020
Corometrics Model: 4033CAX – K934959
Datascope Model: 0012-00-0516-02 – K97006 & K993531
GE Medical Systems Model: E9004GE & 2006644-001 – K012467 & K033304
Nellcor: MC10 – K991823, K993637 & K973147
Nellcor: DEC8 – K971946
Nellcor: SCP10 – K991823, K993637 & K973147
Phillips Model: M1940A – K014159
Phillips Model: M1941A – K993383
Phillips Model: M1943A – K021453
Spacelabs Model: 700-0002-00 – K901209
Spacelabs Model: 700-0030-00 – K972502
Spacelabs Model: 175-0646-00 – K901209
Spacelabs Model: 700-0029-00 – K972502

Description:

AIV's Pulse Oximeter Adapter Cables are direct replacements for similar cables manufactured by the Original Equipment Manufacturers (OEM) for their respective monitors. They use the same type of construction and have the same technological characteristics as the predicate devices (OEM).

The OEM monitors are used for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.

The adapter cable connects the OEM pulse oximeter sensor with the OEM monitor.

Intended Use:

These devices are intended to be used as replacement accessories to Original Equipment Manufacturer monitors used in the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. These systems are used to monitor patients who are either well or poorly perfused, in hospitals, hospital type facilities, intra-hospital transport and home environments.

Comparison to Predicate Device:

	AIV	**OEM**
Intended Use	The adapter cable connects the OEM pulse oximeter sensor with the OEM monitor for continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.	Same
Type of Construction	Flexible, shielded, multi conductor electrical cable.	Same
Connector Design	Adapter cable connectors are keyed to fit the appropriate monitors.	Same
Installation into system	Installed in system between monitor and sensor using keyed connectors.	Same
Target Patient Population	Patients that are well or poorly perfused.	Same
Patient Use/Reuse	Reusable.	Same
Sterility	Non-sterile.	Same
IEC 60601-1 Testing	Passed Safety Testing.	Same
IEC 60601-1-2 Testing	Passed or when OEM system not passing with AIV cable, then OEM system tested with OEM adapter cable to show AIV equivalent to OEM adapter cable.	Same

Performance Data and Conclusions:

- AIV design is equivalent to predicate device design.
- Bench Testing demonstrates that the AIV devices perform as intended.
- The company has declared conformity to consensus standards relating to Electrical/EMC/Mechanical/Safety
- These devices do not raise new issues of safety and effectiveness, nor do they alter the fundamental technology of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2006

Mr. Gregory Falk
Director of Regulatory Affairs and Quality Assurance
American I.V. Products, Incorporated
7485 Shipley Avenue
Hanover, Maryland 21076

Re: K052544
Trade/Device Name: Pulse Oximeter Adapter Cables
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 5, 2006
Received: September 6, 2006

Dear Mr. Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Pulse Oximeter Adapter Cables

Indications For Use:

These devices are intended to be used as replacement accessories to Original Equipment Manufacturer monitors used in the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. These systems are used to monitor patients who are either well or poorly perfused, in hospitals, hospital type facilities, intra-hospital transport and home environments.

AIV Part #	OEM Part #	OEM Monitor use
CBCSI	518DD	Criticare 504DX, 506DX & Alaris 8100
CBCORO	4033CAX	Corometrics 118 and Fetal Center Monitor
CBDAT	0012-00-0516-02	Datascope Passport, Accutor Plus, Sat 3 & Sat 4
CB10640	E9004GE 2006644-001	GE Medical Systems Solar 8000M & 9500M, Solar Tram Modules T451N & T851N, Dash 2000, 3000 & 4000
CB10587	MC10	Nellcor NPB-290, NPB-295 & N-395
CB10588	DEC8	Nellcor N-20, NPB-40, NPB-75, NPB-190 Welch Allyn Protocol Propaq Most BCI Monitors
CB10641	SCP10	Nellcor NPB-290, NPB-295, N395 & N-3000
CBHPHP1	M1940A	Philips M1175A, M1176A, 78352A, 78352C, 78354A, 78354C, 7833A, M78833B, M1722A, M1722B, M1723A, M1723B, & M2475B
CB10586	M1941A	Philips M3000A Viridia, M3500B Heartstream XLT Defib/Monitor & M4735A XL Defib/Monitor
CB10590	M1943A	Philips M2601A Viridia, M3000A Viridia, M3500B Heartstream XLT Defib/Monitor & M4735A XL Defib/Monitor
CBSP1	700-0002-00	Spacelabs Monitors with modules: 90351-D/G, 90465/66/67, 90489, 90651-A & 90651-08
CBSP2	700-0030-00	Spacelabs Ultraview 1050, 1600, 1700 & all monitors using Ultraview Command Module 90496

CBSPNV1	175-0646-00	Spacelabs Monitors with modules: 90351-D/G, 90465/66/67, 90489 90651-A & 90651-08
CBSPNV2	700-0029-00	Spacelabs Ultraview 1050, 1600, 1700 & all monitors using Ultraview Command Module 90496

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Div Off)
Anesthesiology, General Hosp
Dental Devices
Number K052544